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| EXAMINER |
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CROW, ROBERT THOMAS

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1634

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/568,507 | Applicant(s) YAMAMOTO, NOBUKO | |
| | Examiner Robert T. Crow | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-11 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 9-11, and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>09/09/09</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 9 November 2009 in which claim 1 was amended, no claims were canceled, and no new claims were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph, are maintained and are reiterated below.

The previous rejections under 35 U.S.C. 102(a,b,e) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments.

Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1, 9-11, and 22-25 are under prosecution.

Information Disclosure Statement

2. The Information Disclosure Statement filed 9 September 2009 is acknowledged. However, the documents are lined through to avoid duplication on the record, as they were previously cited on the PTO Form 892 mailed 26 March 2008 and on the PTO Form 892 mailed 16 July 2008.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 22 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained from the previous Office Action.

A. Claims 22 and 24 are indefinite in claim 22, which recites the limitation "based on expected amounts of the target substances in the solution" at the end of the claim. The recitation is indefinite because the number of probe spots depends upon expected amounts in a solution, which not part of the claimed carrier, and which is dependent the target solution used and can vary between different target solutions. For example, a carrier having a first area has ten spots to a first gene and a second area having twenty spots to a second gene. A target solution has twice as much expression of the second gene as the first, and the carrier infringes upon the claim. A second target solution has equal amounts of expression in both genes. Thus, the same carrier that infringes upon the claim if used with the first target solution does not infringe upon the claim if used with the second target solution. The metes and bounds of the claims are thus unclear because the same carrier infringes claim 22 if it is used with the first target solution but does not infringe claim 22 if it is used with the second target solution. Therefore, infringement could not be assessed and the claim is indefinite.

B. Claim 24 is indefinite because the term "practically" in claim 24 is a relative term which renders the claim indefinite. The term "practically" is not defined by the claim, the specification does not provide a standard for

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ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, the recitation “practically equal” is indefinite because the metes and bound of “practically” (e.g., +/- 10%, 15% etc) are not defined either by the claim or the specification.

C. Claim 25 is indefinite in the limitation “wherein the number of spots in each of the areas is proportional to an average amount of expression, in a human, of a target gene having a sequence complementary to a respective one of the probes” at the end of the claim. The recitation is indefinite because the number of probe molecules depends on the amount of target in a human, wherein the amount of target is “a human” is dependent upon which human is used and can vary between different human subjects. For example, a carrier having a first area has ten spots to a first gene and a second area having twenty spots to a second gene. A first human subject has twice as much expression of the second gene as the first, and the carrier infringes upon the claim. A second human subject has equal amounts of expression in both genes. Thus, the same carrier that infringes upon the claim if used with the first human patient does not infringe upon the claim if used with the second human patient. The metes and bounds of the claims are thus unclear because the same carrier infringes claim 24 if it is used with the first human but does not infringe claim 24 if it is used with the second human. Therefore, infringement could not be assessed and the claim is indefinite.

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5. The following rejections are new rejections necessitated by the amendments.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 9-10, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan et al (Biosensors and Bioelectronics, vol. 18. pages 1455-1459, available online 2 April 2003; as evidenced by the Biosensors and Bioelectronics homepage at sciencedirect.com [retrieved on 2010-02-02]) in view of Kronick et al (U.S. Patent Application Publication No. US 2004/0115722 A1, published 17 June 2004, filed 25 November 2003)

Regarding claim 1, Sheehan et al teach a probe carrier in the form of a biomolecule array, which has a gold surface (page 10456, Section 2.2) having separated spots at known locations on the carrier (Figure 2). The spots have a uniform diameter (page 1457, column 2, second full paragraph), and are produced from a 3 micromolar solution (page 1456, Section 2.2).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is

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shifted to the applicants to “prove that subject matter shown to be in the prior art does not possess characteristic relied on” (205 USPQ 594, second column, first full paragraph). While Sheehan et al do not explicitly teach each of the four different ssDNA probes in Figure 2 are spotted from solutions having the same concentrations, Sheehan et al only disclose one solution concentration for spotted DNA probes (page 1456, Section 2.2). Thus, Sheehan et al either teach all of the probes are spotted at the same concentration, or it would be obvious because Sheehan et al do not indicate that different concentrations are utilized.

Sheehan et al do not teach spots are for different genes, or that the number of spots differs depending on the genes.

However, Kronick et al teach a probe carrier comprising a carrier in the form of a solid support (Abstract and Figure 6) having thereon a plurality of probe spots (i.e., features; paragraph 0063). The array comprises different regions, wherein each region comprises multiple features (paragraph 0014), and each feature is a spot (paragraph 0030). The address of each spot, feature, and region is known because the array is fabricated (paragraph 0030). Kronick et al teach different probes that are capable of specifically binding to a target substance (paragraph 0090), and the probes bind to genes (paragraph 0166). Kronick et al also teach the relative total feature areas (i.e., regions) have different numbers of features of the same size and that the population of probes therein are dependent upon the suspected relative abundance of the targets (paragraph 0090); thus, the carrier comprises two different areas (regions) comprising features (spots) to different genes, and the number of spots in each region is

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different because the number of spots depends on the expected abundance of the target detected in each area. Kronick et al also teach the number of spots has the added advantage of allowing the detection signals from the array to be optimized for specific targets (paragraph 0093). Thus, Kronick et al teaches the known technique of having spots for different genes, and that the number of spots differs depending on the genes.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the probe carrier as taught by Sheehan et al so that the spots of the probe carrier comprise spots for different genes and so that the number of spots differs depending on the genes in accordance with the teachings of Kronick et al to arrive at the instantly claimed probe carrier with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a probe carrier having the added advantage of allowing the detection signals from the array to be optimized for specific targets as explicitly taught by Kronick et al (paragraph 0093). In addition, it would have been obvious to the ordinary artisan that the known technique of having spots for different genes, and that the number of spots differs depending on the genes, as taught by Kronick et al could have been applied to the probe carrier of Sheehan et al with predictable results because the known technique of having spots for different genes, and that the number of spots differs depending on the genes, as taught by Kronick et al predictably results in probe numbers and spot numbers suitable for genetic assays.

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Regarding claim 9, the carrier of claim 1, is discussed above. Kronick et al teach wherein the amount of probe molecules per spot is the same for the same probe and different between probes having different sequences; namely, features within a region have the same probe density and the different regions have different probe densities (paragraph 0014). Thus, modification of the carrier of Sheehan et al with the teachings of Kronick et al results in a carrier wherein the amount of probe molecules per spot is the same for the same probe and different between probes having different sequences.

Regarding claim 10, the carrier of claim 1 is discussed above.

It is noted that the courts have stated:

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP§ 2113.

While neither Sheehan et al nor Kronick et al specifically teach ink jetting, these limitations are part of the process of making the probe carrier rather than structural limitations of the probe carrier. Because the prior art teaches the structural elements of claim 1, claim 10 is also obvious over the prior art.

Regarding claim 22, the carrier of probe 1 is discussed above. Kronick et al teach wherein the number of spots is higher for a target that is expected to be at a higher ratio than the number of spots for a target that is expected to be at a lower ratio; namely, the number of probes is proportional to the square root of the

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expected signal for each target (paragraph 0097). Thus, modification of the carrier of Sheehan et al with the teachings of Kronick et al results in a carrier wherein the number of spots is higher for a target that is expected to be at a higher ratio than the number of spots for a target that is expected to be at a lower ratio

Regarding claim 23, the carrier of probe 1 is discussed above. Kronick et al also teach the amount of probes immobilized per spot is known; namely, 6×10^{10} probes per spot (i.e., feature) is immobilized (paragraph 0097). Thus, modification of the carrier of Sheehan et al with the teachings of Kronick et al results in a carrier wherein the amount of probes immobilized per spot is known.

Regarding claim 24, the carrier of probe 22 is discussed above. Kronick et al further teach the amount of probe molecules per spot is practically equal among all probes; namely, the different regions have the same feature probe density (i.e., numbers of probes per feature; paragraph 0063), but different numbers of features of the same size (paragraph 0090). Thus, modification of the carrier of Sheehan et al with the teachings of Kronick et al results in a carrier wherein the amount of probe molecules per spot is practically equal among all probes.

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8. Claims 11 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan et al (Biosensors and Bioelectronics, vol. 18. pages 1455-1459, available online 2 April 2003; as evidenced by the Biosensors and Bioelectronics homepage at sciencedirect.com [retrieved on 2010-02-02]) in view of Kronick et al (U.S. Patent Application Publication No. US 2004/0115722 A1, published 17 June 2004, filed 25 November 2003) as applied to claims 1 and 23 above, and further in view of Ares et al (U.S. Patent Application Publication No. US 2004/0009512 A1, published 15 January 2004, filed 25 April 2003).

Regarding claim 11, the probe carrier of claim 1 is discussed above in Section 7.

Neither Sheehan et al nor Kronick et al specifically teach the maximum number of spots in the arrays differs 100 to 1000 times.

However, Ares et al teach arrays comprising a plurality of different oligonucleotide spot patterns, wherein each spot pattern is to a different target nucleic acid (paragraph 0072), and that the number of spots of a typical array is about twenty or about twenty thousand (paragraph 0071), which has the added advantage of being useful in high throughput applications (paragraph 0072). Thus, Ares et al teach the known technique of providing spot densities having 1000-fold differences.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the carrier of Sheehan et al in view of Kronick et al so that range of the number of spots is such that the first area has 20 probes and another area has 20,000 probes as

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taught by Ares et al to arrive at the instantly claimed carrier with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a carrier having the added advantage of being useful in high throughput applications as explicitly taught by Ares et al (paragraph 0072). In addition, it would have been obvious to the ordinary artisan that the known technique of having spot arrays having ranges of spot numbers of 1000 times difference of Ares et al could have been applied to the carrier of Sheehan et al in view of Kronick et al with predictable results because the known technique of having spot arrays having ranges of spot numbers of 1000 times difference of Ares et al predictably results in a reliable array configuration for detecting target molecules.

Regarding claim 25, the carrier of claim 23 is discussed above in Section 7.

Sheehan et al do explicitly teach the number of spots in each area is proportional to an average amount of expression of the gene.

However, Kronick et al teach a carrier having different regions, wherein each region comprises multiple features (paragraph 0014), and each feature is a spot (paragraph 0030). The addresses of each spot, feature, and region are known because the array is fabricated (paragraph 0030). Kronick et al teach different probes that capable of specifically binding to a target substance (paragraph 0090), and the probes bind to genes (paragraph 0166). Kronick et al also teach the relative total feature areas (i.e., regions) have different numbers of features of the same size and that the population or probes therein are

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dependent upon the suspected relative abundance of the targets (paragraph 0090), wherein the number of probes is proportional to the square root of the expected (i.e., average) signal for each target (paragraph 0097). Kronick et al also teach the probe densities have the added advantage of allowing customized arrays to be made for a target (paragraph 0076). Thus, Kronick et al teach the known technique of providing amounts of probe molecules so that number of spots is proportional to an average (i.e., expected) amount of target gene in a sample.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the carrier comprising probe spots as taught by Sheehan et al in view of Kronick et al so that number of spots is proportional to the expected average amount of a target as taught by Kronick et al to arrive at the instantly claimed carrier with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a carrier having the added advantage of allowing customized arrays to be made for a target as explicitly taught by Kronick et al (paragraph 0076). In addition, it would have been obvious to the ordinary artisan that the known technique of providing amounts of probe molecules so that number of spots is proportional to the average amount in the sample as taught by Kronick et al could have been applied to the carrier as taught by Sheehan et al in view of Kronick et al with predictable results because the known technique of providing amounts of probe molecules so that number of spots is proportional to the average amount in

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the sample as taught by Kronick et al predictably results in an array configuration useful in detecting genes.

Neither Sheehan et al nor Kronick et al teach the probes are for human genes.

However, Ares et al teaches a carrier that comprises spots for gene expression (paragraph 0062) and that the spots correspond to human genes, which has the added advantage of allowing detection of genes implicated in cancer (paragraph 0076). Thus, Ares et al teach the known technique of having spots for measuring human gene expression.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the carrier of Sheehan et al in view of Kronick et al so that the spots are to human gene expression as taught by Ares et al to arrive at the instantly claimed carrier with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a carrier having the added advantage of allowing detection of genes implicated in cancer as explicitly taught by Ares et al (paragraph 0076). In addition, it would have been obvious to the ordinary artisan that the known technique of providing of spots for human gene expression as taught by Ares et al could have been applied to the carrier of Sheehan et al in view of Kronick et al with predictable results because the known technique of providing of spots for human gene expression as taught by Ares et al predictably results in an carrier useful for studying human genetic diseases.

Response to Arguments

9. Applicant's arguments filed 9 November 2009 (hereafter the "Remarks") have been fully considered but they are not persuasive for the reasons discussed below.

A. Applicant argues on pages 4-5 of the Remarks that claim 22 is not indefinite because the probe carrier can be used for two or more genes having expression levels which are known to be different.

However, as noted above, the recitation is indefinite because the number of probe spots depends upon expected amounts in a solution, which are not part of the claimed carrier, and which is dependent the target solution used and can vary between different target solutions. For example, a carrier having a first area has ten spots to a first gene and a second area having twenty spots to a second gene. A target solution has twice as much expression of the second gene as the first, and the carrier infringes upon the claim. A second target solution has equal amounts of expression in both genes. Thus, the same carrier that infringes upon the claim if used with the first target solution does not infringe upon the claim if used with the second target solution. The metes and bounds of the claims are thus unclear because the same carrier infringes claim 22 if it is used with the first target solution but does not infringe claim 22 if it is used with the second target solution. Therefore, infringement could **not** be assessed and the claim is indefinite.

B. Applicant argues on page 5 of the Remarks that claim 24 is not indefinite because if the number of probe molecules per spot does not vary

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“significantly,” and the difference in the immobilized mount is “substantially realized” that the number of probe molecules should be deemed “practically” equal.

However, as noted above, the term “practically” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, the recitation “practically equal” is indefinite because the metes and bound of “practically” (e.g., +/- 10%, 15% etc) are not defined either by the claim or the specification.

In addition, it is noted that Applicant’s arguments also rely on relative terms (i.e., “significantly” and “substantially realized”) neither required by the claim, nor defined by either the claim or the specification. Thus, neither the claim nor Applicant’s arguments provide any guidance as to the metes and bounds of the claimed limitation.

C. Applicant also argues on page 5 of the Remarks that claim 25 is not indefinite because the average amounts of expression of some human genes are generally known, even though the amount might vary to some extent.

However, as discussed above, Applicant's own arguments are the reason the claim is indefinite; namely, because the number of probe molecules depends on the amount of target in a human, wherein the amount of target is “a human” is dependent upon which human is used and can vary between different human subjects. For example, a carrier having a first area has ten spots to a first gene and a second area having twenty spots to a second gene. A first human subject

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has twice as much expression of the second gene as the first, and the carrier infringes upon the claim. A second human subject has equal amounts of expression in both genes. Thus, the same carrier that infringes upon the claim if used with the first human patient does not infringe upon the claim if used with the second human patient. The metes and bounds of the claims are thus unclear because the same carrier infringes claim 24 if it is used with the first human but does not infringe claim 24 if it is used with the second human. Therefore, infringement could **not** be assessed and the claim is indefinite.

D. Applicant's remaining arguments on pages 5-7 of the Remarks refer to the previous rejections of the claims. These arguments have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Robert T. Crow
Primary Examiner
Art Unit 1634

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